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09/840,669	04/23/2001	Tadahiko Kohno	A-690	4141

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EXAMINER
KAM, CHIH MIN

ART UNIT	PAPER NUMBER
1653	13

DATE MAILED: 07/15/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 09/840,669	Applicant(s) KOHNO, TADAHIKO	
	Examiner Chih-Min Kam	Art Unit 1653	

-- The MAILING DATE of this communication appears on the c ver sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____ .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-31* is/are pending in the application.

4a) Of the above claim(s) *14-31* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-13* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) *4,12* .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

DETAILED ACTION

Election/Restrictions

1. Restriction to one of the following inventions is required under 35 U. S. C. 121:

I. Claims 1-13, drawn to a composition of matter having formula $(A^1)_a$-F^1-$(A^2)_b$ and multimers thereof, wherein F^1 is a vehicle; A^1 and A^2 each contains peptide sequences of Apo-AI amphipathic helix peptide or amphipathic helix peptide-mimetic domains and linkers, classified in class 514, subclass 12, and class 530, subclass 350.

II. Claims 14-27, drawn to a DNA encoding a composition of matter having formula $(A^1)_a$-F^1-$(A^2)_b$ and multimers thereof; an expression vector comprising the DNA; a host cell comprising the expression vector; and a method for preparing an Apo-AI amphipathic helix peptide or amphipathic helix peptide-mimetic compound by expression of DNA in the host cell, classified in class 536, subclass 23.1, and class 435, subclasses 320.1 and 325.

III. Claim 28, drawn to a method of treating hypercholesterolemia comprising administering a composition of matter having formula $(A^1)_a$-F^1-$(A^2)_b$ and multimers thereof, classified in class 514, subclass 12, and class 530, subclass 350.

IV. Claims 29-31, drawn to a method of treating viral infection comprising administering a composition of matter having formula $(A^1)_a$-F^1-$(A^2)_b$ and multimers thereof, classified in class 514, subclass 12, and class 530, subclass 350.

2. The inventions are distinct, each from the other because of the following reasons:

The DNA of Invention II is related to the peptide of Invention I by virtue of encoding same. Although the DNA molecule and the peptide are related, they are distinct inventions

because they are physically and functionally distinct chemical entities and have different utilities. For example, the peptide can be made by another and materially different process such as by chemical synthesis, and DNA can be used for making probes in northern or southern hybridization.

The process of Invention II and the peptide of Invention I are related as process of making and product made. The inventions are distinct if either or both of the following can be shown: (1) that the process as claimed can be used to make other and materially different product or (2) that the product as claimed can be made by another and materially different process (MPEP § 806.05(f)). In the instant case the peptide of Invention I can be made by chemical synthesis.

The product of Invention I and the methods of Inventions III and IV are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case, the methods of Inventions III and IV are alternative processes of use of the product of Invention I.

The product of Invention II is distinct from the methods of Inventions III and IV because the product of Invention II can be neither made by nor used in the methods of inventions III and IV.

The methods of Inventions II, III and IV are patentably distinct each from the other because they have different method steps, utilize different materials and produce different results.

Because these inventions are distinct for the reasons given above and have acquired a separate status in the art as shown by their different classification and their recognized divergent subject matter, and because each invention requires different searches but are not co-extensive, examination of these distinct inventions would pose a serious burden on the examiner and therefore restriction for examination purposes as indicated is proper.

Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement is traversed (37 CFR 1.143).

During a telephone conversation with Timothy Gaul on April 8, 2003 a provisional election was made with traverse to prosecute the invention of Group I, claims 1-13. Affirmation of this election must be made by applicant in replying to this Office action. Claims 14-31 are withdrawn from further consideration by the examiner, 37 CFR 1.142(b), as being drawn to a non-elected invention.

Informalities

The disclosure is objected to because of the following informalities:

3. The specification indicates there are Fig. 4 (page 21, line 22), and Figs. 5 and 6 (page 23, line 2), however, the drawings only have Figs. 1-3. Appropriate correction is required.

Claim Objections

4. Claim 13 is objected to because the claim indicates the composition having a sequence selected from Table 2 (SEQ ID NOs: 8-11), the term "Table 2" should not cited in the claim. Use of the term "a sequence selected from the group consisting of SEQ ID NOs: 8, 9, 10 and 11" is suggested.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

5. Claims 1-13 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 1-13 are indefinite because of the use of the term "Apo-AI". The term "Apo-AI" renders the claim indefinite, it is unclear what the term means. A full spelled out word should be indicated in the first occurrence. Claims 2-13 are included in this rejection for being dependent on a rejected claim and not correcting the deficiency of the claim from which they depend.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
> (a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.
> (e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

The changes made to 35 U.S.C. 102(e) by the American Inventors Protection Act of 1999 (AIPA) and the Intellectual Property and High Technology Technical Amendments Act of 2002 do not apply when the reference is a U.S. patent resulting directly or indirectly from an international application filed before November 29, 2000. Therefore, the prior art date of the

reference is determined under 35 U.S.C. 102(e) prior to the amendment by the AIPA (pre-AIPA 35 U.S.C. 102(e)).

6. Claim 1 is rejected under 35 U.S.C. 102(b) as being anticipated by Nion *et al.* (Atherosclerosis 227-235 (1998)).

Nion *et al.* teach three apoAI(145-183) units are synthesized as a trimer, where each unit is composed of two amphipathic helical segments (page 228, paragraph 2.2; Fig. 1). It appears the trimer has the structure of A^1-F^1-A^2, where A^1 is P^1-(L^2)-P^2, F^1 is the vehicle of polylysine, A^2 is P^1, and c=0 for $(L^1)_c$ (Fig 1; claim 1). Since the claim does not identify the structure of vehicle, a peptide of polylysine can be a vehicle.

7. Claim 1-3 and 9 are rejected under 35 U.S.C. 102(e) or 102 (a) as being anticipated by Dasseux *et al.* (U. S. Patent 6,046,166, filed September 29, 1997).

Dasseux *et al.* teach ApoA-I agonists are peptides or analogs thereof capable of forming amphipathic α-helices in the presence of lipids (column 14, lines 15-22), where peptides comprises formula (I) (columns 15 and 211), formula (IV) or (V) (columns 33 and 34). In formula (IV) or (V), where X is HH-$(LL_m$-$HH)_n$-LL_m-HH, HH is core peptide of formula I, LL is bifunctional linker, thus formula (IV) or (V) has the structure of A^1-F^1-A^2, where F^1 is the vehicle of polylysine, and A^1 and A^2 is X (claim 1). SEQ ID NO:244 (column 39, lines 21-22) which has the same sequence of SEQ ID NO:7 of the instant application is used as the core peptide in formula (I), (IV) or (V) (claim 9). In formula (I) of claim 1 (column 211), where Z_1 is RCONH-, X_1....X_{23} is the core peptide, Z_2 is –CONRR, -COOR or -COOH, where R can be 1-7 residue peptide, thus, formula (I) can be F^1-A^2 or F^1-$(L^1)_c$-P^1, where F^1 is the vehicle of R, and A^2 is the linker (CO-NH) with the core peptide of X_1....X_{23} (claims 2 and 3). Since the claim

does not identify the structure of vehicle, a peptide of 7 amino acid residues or polylysine can be a vehicle.

Conclusion

8. No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Chih-Min Kam whose telephone number is (703) 308-9437. The examiner can normally be reached on 8.00-4:30, Mon-Fri.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christopher Low, Ph. D. can be reached on (703) 308-2923. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 308-0294 for regular communications and (703) 308-4227 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.

Chih-Min Kam, Ph. D. CMK
Patent Examiner

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July 10, 2003

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